UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re INTERCEPT PHARMACEUTICALS, INC. SECURITIES LITIGATION	Civil Action No. 1:14-cv-01123-NRB
	CLASS ACTION
This Document Relates To: ALL ACTIONS.	CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS
	DEMAND FOR JURY TRIAL

1. George Burton ("Burton" or "Plaintiff"), by his undersigned counsel, hereby brings this action on behalf of himself and all persons or entities who purchased or otherwise acquired the common stock of Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company") during January 9 through January 10, 2014, inclusive (the "Class Period"), and were damaged thereby. Excluded from the Class, as defined below, are Defendants, present or former executive officers of Intercept and their immediate family members (as defined in 17 C.F.R. §229.404, Instructions (1)(a)(iii) and (1)(b)(ii)). As detailed herein, Plaintiff seeks to recover damages caused by Defendants' violations of §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Plaintiff alleges the following based upon personal knowledge as to himself and his own acts and upon information and belief as to all other matters. Plaintiff's information and belief is based on, *inter alia*, the independent investigation of his counsel, Robbins Geller Rudman & Dowd LLP and Pomerantz LLP. This investigation included, but was not limited to, a review and analysis of: (i) records of communications between Defendants and representatives of the National Institutes of Health ("NIH") and the NIH's National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"); (ii) Intercept's public filings with the Securities and Exchange Commission ("SEC"); (iii) transcripts of Intercept's public conference calls; (iv) Intercept's press releases; (v) independent media reports regarding Intercept and the NIDDK; (vi) economic analyses of Intercept's stock price movement and pricing and volume data; (vii) consultations with relevant experts; and (viii) other publicly available material and data identified herein. Counsel's investigation into the factual allegations contained herein is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Plaintiff believes that additional

evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION AND OVERVIEW

3. This is a clear-cut case of securities fraud. Intercept was founded in 2002 with the goal of developing and marketing pharmaceutical products. Twelve years later, the Company had not received marketing approval for any drugs and had earned no product revenue. It did, however, have one promising product candidate, obeticholic acid ("OCA"). Defendants hoped to market OCA for a host of liver ailments and had the drug in clinical trials for the treatment of nonalcoholic steatohepatitis ("NASH") and primary biliary cirrhosis ("PBC") in 2013. Getting positive clinical trial results and bringing OCA to market for either indication would mean billions of dollars in annual revenue.

4. The trial for OCA as a treatment for NASH, known as the FLINT trial, was being conducted by the NIDDK. On January 6, 2014, the NIDDK scheduled a call with defendant David Shapiro ("Shapiro") to discuss the FLINT trial. During that call, according to emails and records of communications between Defendants and the NIDDK obtained through a Freedom of Information Act request, the NIDDK told Shapiro both good news, the FLINT trial was being stopped because the drug had demonstrated efficacy, and bad news, the trial was also being stopped because of a "finding of significant lipid abnormalities (increased total cholesterol, increased LDL cholesterol and decreased HDL cholesterol)" in patients on OCA compared to those on placebo. Defendant Shapiro acknowledged that he was aware of serious adverse event reports that had come out of the FLINT trial and told the NIDDK that Intercept would publicly disclose that the trial had been stopped "on the basis of efficacy and that lipid abnormalities have been observed."

5. Three days later, on the morning of January 9, 2014, Intercept issued a press release about the stopping of the FLINT trial. Defendants reported the positive news about the efficacy of OCA, but failed to report the negative news about the finding of significant lipid abnormalities. Following the close of the market on January 9, 2014, Defendants hosted a conference call with analysts and investors regarding the FLINT trial. Defendants provided more information about the efficacy findings in the trial but, again, made no disclosure about the finding of significant lipid abnormalities associated with OCA in the treatment of NASH.

6. In response to Defendants' false and misleading statements about the FLINT trial, Intercept's stock price skyrocketed. From January 9 to January 10, 2014, Intercept's stock price increased $373.44 per share, from $72.39 to $445.83, as more than 12 million shares changed hands.

7. Following the close of the market on January 10, 2014, a Friday, defendant Shapiro received another email from the NIDDK. This time, the NIDDK said that, in response to Defendants' statements and numerous media requests, the agency was going to take the unusual step of issuing its own statement and identify the finding of lipid abnormalities in the FLINT trial. Shapiro desperately tried to stop or delay the NIDDK's statement, emailing the NIDDK that "[t]he lipid information is specific and I think will cause issues," but the statement was issued on the evening of January 10. The NIDDK's statement was immediately covered by news organizations and by Sunday, January 12, Intercept had issued its own statement conceding the accuracy of the NIDDK's disclosure regarding lipid abnormalities, but suggesting that Defendants had no knowledge of the negative effects of OCA at the time they had made their statements on the positive OCA efficacy results.

8. The reaction to the NIDDK's disclosure was swift and severe. In the trading days immediately following the release, January 13 and January 14, 2014, Intercept's stock price plunged $190.71 per share on volume far exceeding the Company's average.

9. Four months later, on May 20, 2014, an early morning media report unveiled the NIDDK's communications with Intercept prior to January 9, 2014 and demonstrated that Defendants were fully apprised of the negative safety issues associated with the FLINT trial at the time of their positive public statements. As *The Wall Street Journal* reported, "Intercept was aware as early as Jan. 6 that the cholesterol issue played a role in the NIH's decision to stop the study," but "[w]hen Intercept issued its news release on Jan. 9 disclosing that the study was stopped early for efficacy, there was no mention of cholesterol abnormalities or any potential side effects."

10. As a result of the May 20, 2014 disclosure regarding Defendants' fraudulent conduct, Intercept's stock price dropped another 14.1% to $223.34 per share. All told, those investors who purchased Intercept stock on January 9 and January 10, 2014, following Defendants' false and misleading statements regarding the FLINT trial, individually suffered damages up to $227.37 per share and collectively suffered hundreds of millions of dollars in damages.

II. JURISDICTION AND VENUE

11. This Complaint asserts claims under §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. §240.10b-5.

12. This Court has jurisdiction over the subject matter of this action under §27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §1331, because this is a civil action arising under the laws of the United States.

13. Venue is proper in this District under §27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §1391(b)-(d). Many of the acts and transactions that constitute the alleged violations of law, including the dissemination to the public of untrue statements of material facts, occurred in this District where the Company's stock actively trades on the Nasdaq Stock Market.

14. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications, and the facilities of national securities exchanges.

III. THE PARTIES

15. **George Burton**: Plaintiff Burton is a resident of Northbrook, Illinois. As set forth in the certification already on file with the Court and attached hereto as Exhibit A, Burton purchased Intercept common stock on the Nasdaq during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

16. **Intercept**: Defendant Intercept is a biopharmaceutical company. The Company was, at all relevant times, incorporated in Delaware, and maintained headquarters and research and development operations in New York, New York and San Diego, California. Intercept became a publicly traded company through an initial public offering conducted in October 2012 and trades in an efficient market on the Nasdaq, under the symbol "ICPT." In the six months prior to the Class Period, Intercept's stock traded in the range of $45 to $70 per share and the average daily trading volume was 443,000 shares. Intercept, through its management, representatives and agents, made and is liable for, the misstatements and omissions set forth herein at ¶¶37-38, 41-43.

17. **Dr. Mark Pruzanski**: Defendant Dr. Mark Pruzanski ("Pruzanski") worked out of Intercept's New York facilities, and was, at all relevant times, the Chief Executive Officer ("CEO")

and President of Intercept and served on the Company's Board of Directors. Pruzanski received his M.D. from McMaster University in Hamilton, Ontario and a bachelor's degree from McGill University in Montreal, Quebec. Intercept's April 12, 2013 Proxy Statement emphasized Pruzanski's "perspective and the experience" as CEO and "his historic knowledge of our company and our product candidates, operational expertise . . . , and his experience in managing and investing in companies within the life sciences industry."

18. Prior to the Class Period, Pruzanski approved and signed Intercept's Code of Conduct and Ethics. The Code of Conduct and Ethics required that the Company's officers and employees ensure "[r]eports and other documents . . . state all material facts of a transaction and not omit any information that would be relevant in interpreting such report or document" and defined material information as "information that a reasonable investor would consider important in making his or her investment decisions, or information that is likely to have a significant effect on the price of the company's securities."

19. Pruzanski made or had authority over the content, and how to communicate it, of the misstatements and omissions set forth herein at ¶¶37-38, 41-43, and is liable for those misstatements and omissions. Pruzanski is also liable as a control person of Intercept within the meaning of §20(a) of the Exchange Act.

20. **Dr. David Shapiro**: Defendant Shapiro worked out of Intercept's San Diego, California facilities, and was, at all relevant times, Chief Medical Officer and Executive Vice President, Development of Intercept. Shapiro received his M.D. from Dundee University & Medical School in the United Kingdom and, prior to joining Intercept in 2008, was CEO and President of a biopharmaceutical consulting company, Integrated Quality Resources, and the Chief Medical Officer of Idun Pharmaceuticals.

21. Prior to the Class Period, Shapiro approved and signed Intercept's Code of Conduct and Ethics. The Code of Conduct and Ethics required that the Company's officers and employees ensure "[r]eports and other documents . . . state all material facts of a transaction and not omit any information that would be relevant in interpreting such report or document" and defined material information as "information that a reasonable investor would consider important in making his or her investment decisions, or information that is likely to have a significant effect on the price of the company's securities."

22. Shapiro made or had authority over the content, and how to communicate it, of the misstatements and omissions set forth herein at ¶¶37-38, 41-44 and is liable for those misstatements and omissions. Shapiro is also liable as a control person of Intercept within the meaning of §20(a) of the Exchange Act.

IV. BACKGROUND AND PRE-CLASS PERIOD EVENTS

A. Intercept and OCA

23. Intercept is a biopharmaceutical company founded in 2002 by Pruzanski and Roberto Pellicciari, a medicinal chemistry professor at Italy's University of Perugia. As of January 2014, the Company had only developed a single product candidate, OCA, and had not brought any pharmaceutical products to market or generated any product revenue.

24. OCA is a bile acid analog, a chemical substance based on naturally occurring human bile acid. Bile acids are "detergent-like" emulsifying agents that are released from the gallbladder into the intestine when food is ingested, and are necessary for the absorption of dietary cholesterol and other nutrients. Bile acids also mediate biological effects in the body through the activation of certain recepters. The best understood receptor is the farnesoid X receptor ("FXR"), which regulates bile acid synthesis and clearance from the liver, thereby preventing the potentially toxic build-up of

excessive bile acid. In addition, bile acid activation of the FXR induces anti-fibrotic, anti-inflammatory and other mechanisms necessary for liver regeneration.

25. As of January 2014, Defendants were trying to obtain regulatory approval for the marketing of OCA for a number of indications, including for the treatment of NASH, PBC, cirrhosis, primary sclerosing cholangitis, portal hypertension, alcoholic hepatitis and bile acid diarrhea.

B. The Market for OCA as a Treatment for NASH

26. NASH is a disease whereby a fat build-up in the liver causes chronic inflammation which leads to progressive fibrosis, cirrhosis and, possibly, liver failure. Because FXR activation has been shown to play a role in the regulation of the metabolic pathways relevant to NASH, Intercept wanted to market OCA, as an FXR agonist, for the treatment of the disease.

27. According to Intercept's April 21, 2013 Form 10-K, the potential market for a NASH treatment is immense and growing. Studies cited by Intercept claimed that approximately 12% of the general population of the United States is affected by NASH, with similar figures reported in Europe and Japan. There are currently no drugs approved for the treatment of NASH. As a result, any approved treatment option would likely be a pharmaceutical blockbuster due to the size of the demand. Indicative of this untapped market, Intercept's 2013 Form 10-K reported that, in 2010 alone, "there were approximately $615 million in off-label sales of various therapeutics for the treatment of NASH." As an industry observer quoted in *The New York Times* commented with regard to Intercept and OCA, "'NASH is possibly one of the few remaining large untapped markets that we could compare to the LDL [cholesterol] or diabetes market and is rapidly growing.'" Indeed, *The Wall Street Journal* reported that OCA could generate annual sales of $2 billion by 2020 if it made it to market as a treatment for NASH, and Intercept stood to collect billions more if OCA was approved for other indications.

C. The NIDDK and the FLINT Trial

28. OCA, like other pharmaceutical products, was subject to a series of clinical trials to evaluate its effectiveness and safety for a given indication prior to marketing approval. The Phase II clinical trial of OCA for the treatment of NASH, known as the FXR ligand obeticholic acid in NASH treatment trial, or FLINT, was conducted by the NIDDK pursuant to a cooperative research and development agreement ("CRADA") entered into by the NIDDK and Intercept in July 2010. The FLINT trial was, according to defendant Shapiro, "pivotal" to Intercept's goal of gaining the U.S. Food and Drug Administration's ("FDA") approval of OCA for the treatment of NASH, and was only made possible by the NIDDK. The agency provided the majority of resources for the trial and, as Defendants acknowledged, Intercept could never have undertaken such an ambitious trial on its own.

29. The NIDDK is one of 27 different institutes and centers that comprise the NIH. Self-described as "the nation's medical research agency," the NIH's mission is to seek fundamental knowledge regarding living systems and to apply that knowledge to improve public health, prevent disease and to exemplify and promote the highest level of scientific integrity in the conduct of science. To carry out its mission, the NIH and its institutes and centers often work with private businesses in conducting clinical trials of drugs, such as the FLINT trial.

30. According to Intercept, the FLINT trial was "a multi-center, double-blind, placebo-controlled clinical trial assessing the ***safety and efficacy*** of a 25 mg oral dose of OCA administered daily to biopsy-proven adult NASH patients over a 72-week treatment period."[1] The primary endpoint in the FLINT trial was defined as an improvement of two or more points in the

[1] All emphasis is added herein unless otherwise noted.

nonalcoholic fatty liver disease ("NAFLD") activity score (a system of scoring the histopathological features in the liver) with no worsening of liver fibrosis or other safety issues.

31. The NIDDK's reporting duties to the FDA are controlled by the CRADA and FDA regulations, which, in turn, mandated the NIDDK to submit to Intercept "copies of all Safety Reports concurrently with their submission to the FDA, and with any other information affecting the safety" of FLINT patients. As such, under the terms of the CRADA, Intercept received copies of all safety reports submitted to the FDA concerning serious adverse events ("SAEs") and increased rates of serious suspected adverse events within 15 days of the occurrence of any such event.

D. Intercept's Funding of OCA Trials

32. After going public in October 2012, Intercept repeatedly informed investors that it would need additional capital to continue financing OCA clinical trials for NASH and other indications. The Company's June 14, 2013 Form S-1/A registration statement, for instance, told investors "we will require substantial additional funding . . . to complete the development and commercialization of OCA." Intercept's September 30, 2013 Form 10-Q revealed the Company's expenses for pharmaceutical development and various OCA trials had resulted in losses of over $26 million in the first nine months of 2013 and more than $127 million since 2002. While Intercept had completed secondary public offerings in December 2012 and June 2013, raising $78 and $61.2 million, respectively, the Company was continuing to spend heavily on research, development and overhead. As a result, by January 2014, Defendants were planning another secondary offering of Intercept securities to continue funding the Company's operations. That offering was ultimately completed in April 2014. According to the Company's May 9, 2014 SEC Form 10-Q, 1,000,000 shares of common stock were sold, including 400,000 shares sold by insiders, for total net proceeds to the Company exceeding $183 million.

V. THE NIDDK INFORMS DEFENDANTS OF THE OCA EFFICACY AND SAFETY FINDINGS IN THE FLINT TRIAL

33. On January 3, 2014, defendant Shapiro received an email from Averell H. Sherker, M.D. ("Dr. Sherker"), Scientific Advisor for Viral Hepatitis and Liver Diseases for the NIDDK, to set up a call regarding the FLINT trial. On the morning of January 6, 2014, Shapiro confirmed that he would call Dr. Sherker at approximately 12:45 P.M. EST that day.

34. Dr. Sherker's official NIDDK record of the January 6, 2014 call with Shapiro is as follows:

Telephone conversation with Dr. David Shapiro, CSO Intercept Pharma re: FLINT

6 JAN 2014 @ 12:45 EST

Dr. Shapiro called my office from [redacted] upon my request.

He was informed that upon planned interim analysis, the stopping boundary for efficacy was crossed and NIDDK has decided not to have subjects undergo week 72 liver biopsies effective today.

Dr. Shapiro was informed that given this decision and the finding of significant lipid abnormalities (increased total cholesterol, increased LDL cholesterol and decreased HDL cholesterol), all patient [sic] who remain on treatment (OBCA or Placebo) will be discontinued within two weeks of today. Patients will undergo week 72 labs at the treatment close-out visit and patients will be advised to return 24 weeks later for their off-treatment visit.

Dr. Shapiro mentioned that he was aware of SAEs [serious adverse events] as Intercept has been copied on all reports submitted to [the] FDA.

Dr. Shapiro shared that similar abnormalities were seen in [a] study in type 2 diabetics. ***PBC study showed HDL decreases but no LDL increase***. Lipidomic studies (Sanyal, Kowdley and Chalasani) are ongoing and Intercept would be very interested to support further lipid studies in the NASH population.

Intercept has a fiduciary responsible [sic] to publically release Material Information in a timely manner. Intercept has a previously scheduled Quarterly Webinar on January 9 and will mention that NIDDK has informed them that the treatment phase of the study has been terminated on the basis of efficacy and that lipid abnormalities have been observed. Additionally, Intercept will release a press release with the same information. As a courtesy, they will send me the press release for review prior to issuing it.

In discussion, we decided to consider submission of a FLINT abstract as a Late Breaker for EASL. Submission of Late Breakers is open from February 3-10.

35. On January 7, 2014, Shapiro followed up with Dr. Sherker via email concerning Intercept's planned January 9, 2014 disclosure. In that email, as set forth below, Shapiro informed Dr. Sherker that, after conferring with defendant Pruzanski, Intercept intended to issue a press release about the FLINT trial, but would not publicly disclose the significant lipid abnormalities identified by the NIDDK:

> Quite a start to the New Year …. It was good to speak to you yesterday.
>
> ***Following our call, I spoke with Mark Pruzanski, our CEO and we plan to draft a simple press release today that I'll forward to you prior to our release (although SEC regulations bind us to issuing a public statement to within 72 hours). I think that we should just aim to keep the release simple and note [sic] the key points being***:
>
> - NIDDK have informed Intercept that a planned interim efficacy analysis was conducted which showed that OCA produced a highly significant improvement on the protocol specified liver histology endpoint, compared with placebo. The improvement met (p=0.0015) the protocol criterion for stopping the study and accordingly NIDDK have informed Intercept that they are stopping the study.
>
> - Further details will be available when the study is presented at a scientific meeting and/or published and Intercept looks forward to seeing the full results from the study.
>
> - Some background information on NASH – and that there are no approved therapies for this increasingly common disease[.]
>
> ***We don't think that without the specific data, we can comment on the lipid changes. We have previously reported HDL and LDL changes (see attached)***.
>
> If you have any thoughts/disagreements, please let me know ASAP. I'll be interested in hearing what the investigators [sic] response was. As we discussed, we would be very willing to discuss any further collaborations with NIDDK and the group (and would be able to make a decision pretty quickly).
>
> I am in meetings for most of the day but will be on a train for ~4 hours from 10am EST on – so should be available (and I hope I'll have an email connection).

> Again, it is a pleasure collaborating with you on the study and I look forward to moving the study through its conclusion. Thank you.

36. Later on January 7, 2014, Dr. Sherker responded to Shapiro's email and, in pertinent part, wrote:

> ***With respect to the lipid abnormalities, I will defer to you about the decision whether or not to include it in your press release. As I mentioned yesterday, the NIDDK decision to terminate therapy was primarily due to the efficacy effect but, in part, influenced by the significant lipid abnormalities observed in the OCA-treated subjects***.

VI. DEFENDANTS' MISLEADING STATEMENTS AND MATERIAL OMISSIONS

37. Prior to the open of trading on the Nasdaq on Thursday, January 9, 2014, Defendants issued their press release and subsequently filed a Form 8-K, attaching the press release, with the SEC. The press release, which was reviewed and approved for publication by Pruzanski and Shapiro, was entitled "***Intercept Announces NASH Primary Endpoint Met: FLINT Trial Stopped Early for Efficacy Based on Highly Statistically Significant Improvement in Liver Histology***." The press release reported that "the FLINT trial of obeticholic acid (OCA) for the treatment of nonalcoholic steatohepatitis (NASH) ***has been stopped early for efficacy based on a planned interim analysis showing that*** the ***primary endpoint of the trial has been met***."

38. Defendant Pruzanski was quoted in the January 9, 2014 press release as follows:

> "The unexpected ***early stopping of FLINT due to OCA meeting the primary endpoint with such high significance*** is a major milestone . . . . NASH has grown to epidemic proportions worldwide, having become a leading cause of cirrhosis and liver failure. On its current trajectory, the disease is projected to become the leading indication for liver transplant."

There was no mention in the press release of the significant lipid abnormalities identified in the FLINT trial or the fact that these safety issues contributed to the NIDDK's decision to stop the FLINT trial.

39. On January 9, 2014, following Defendants' press release, media outlets repeated and commented positively on the early stopping of the FLINT trial. More than 80 stories were published about Intercept and the FLINT trial in the day following the issuance of the press release. *The New York Times*, as an example, published an article entitled "Promising Drug Trial Lifts Stock of Company," reporting the FLINT study was stopped "because the results were so strikingly in favor of the drug compared with the placebo, according to Intercept."

40. In response to Defendants' press release and the stated positive basis for the early stopping of the FLINT trial, Intercept's stock price increased dramatically, from $72.39 to a close of $275.87 on January 9, 2014. As a January 9, 2014 *Xconomy* article entitled "Intercept Shares Skyrocket After Liver Drug Nails Mid-Stage Study" reported: Intercept's "shares soared more than 230 percent – from a $72.39 Wednesday close to $239.02 – in pre-market trading. Investors are clamoring into the stock after Intercept announced that it stopped a mid-stage clinical trial early because the drug showed such an obvious benefit for liver patients." *Dow Jones* issued an article entitled "Strong Trial Results Boost Shares of Liver Therapy Maker," which similarly provided "[t]he stock of a little-known biotech company, Intercept Pharmaceuticals Inc., more than quadrupled Thursday after a clinical trial of the company's experimental liver-disease therapy was stopped early because patients showed significant improvement." Also on January 9, 2014, a *FierceBiotech* article reported, "[s]hares of Intercept Pharmaceuticals went into overdrive this morning, soaring more than 250% on the surprise news that a Phase IIb clinical study . . . ended early after achieving the primary endpoint," and a *Money Morning* article added, "ICPT shares are up close to 300% and have hit a record high of $305. The reason: Its trial to study [OCA] . . . has been stopped earlier than planned after already meeting the primary endpoint." By the close of the

market on January 9, 2014, Intercept's stock price had increased 281% and the volume of shares traded that day increased over 1,500% to 6.8 million shares.

41. Following the close of trading on January 9, 2014, Defendants held a conference call with analysts and investors to discuss the early stopping of the FLINT trial. Defendants Pruzanski and Shapiro both participated in the conference call. During the call, Pruzanski announced additional positive news regarding the statistical significance of OCA's efficacy in the FLINT trial:

> Let me start then with the news and specifically the FLINT trial, and as many of you know on the call, ***NIDDK, which is a part of the NIH, and has been running and sponsors the FLINT trial informed us that the data safety monitoring board for the FLINT trial recommended stop of the trial early for efficacy. This was based on an interim analysis showing that OCA had met the primary histological endpoint. The decision to stop early was based on a predefined requirement that OCA show a much greater efficacy benefit with better than AP value of 0.0031 on an intention-to-treat basis***. This is certainly a much higher bar to reach than would have been required for final analysis at the end of study.

42. During the January 9, 2014 conference call, Pruzanski further claimed, "[a]t this point, ***NIDDK has only shared the statistical result of the interim efficacy analysis with us, so we don't have additional data to share with you today***. . . . Of course, when we get the data in hand from NIDDK, we will share the results with you." Pruzanski and Shapiro also explained why the early stopping of the FLINT trial was positive news for Intercept and investors:

> [Jim Birchenough – BMO Capital Markets]: And then, maybe just thinking about the opportunity here. Do you have a sense – I haven't looked at this recently – but what the number of patients on the liver transplant wait list is? And, what percentage of those have NASH? I'm just trying to get a sense of the identified patient population by looking at it that way.
>
> [Defendant Pruzanski]: It's a good question. We would have to go back and get some updated information. I think if nothing else, this – almost a year earlier than anticipated result will spur us to expedite our market research here. I can tell you that currently based on the most recent stats I've seen, NASH, at least in the last couple of years has counted for close to about 15% of liver transplants. So, ranking third on the list behind Hep C and alcoholic liver disease, but that . . . is a tenfold increase over the last decade or so. I can't give you the exact numbers, Jim, right

> now, but I will be able to the next time we have a call like this. And, David just wants to adds something.
>
> [Defendant Shapiro]: And, just to emphasize Mark's point, I think that the point being is it is the fastest growing indication for liver transplant is where it is going to end up. We're in the middle of this. We are riding on the front end of this tsunami at the moment, and it is getting more and more every year.

43. At 11:05 A.M. EST on January 10, 2014, following the conference call and an interview with Pruzanski, *The Wall Street Journal* published an article entitled "A $4 Billion Surprise for 45-Person Biotech." In the article, *The Wall Street Journal* reported "***Dr. Pruzanski said the company doesn't yet have details about any adverse events patients might have experienced during***" the FLINT trial. Based on the interview, it was further reported that Pruzanski "***said Intercept was making public all the information it had received from the NIH***." The January 10, 2014 *Wall Street Journal* article also noted that Intercept's market capitalization increased from $1.4 billion to $5.3 billion "after the company announced that a clinical trial of its experimental drug had been halted early because patients showed significant improvement."

44. In response to Defendants' press release and the additional false and misleading statements regarding the early stopping of the FLINT trial in the conference call and related reports following the close of the market on January 9, 2014, Intercept's stock price continued to increase dramatically, reaching an intraday high on January 10, 2014 of $497.00 per share. By the close of the market on January 10, 2014, Intercept common stock traded for $445.83 per share, $169.96 per share higher than the closing price on January 9, 2014. This represented a one-day price increase of 61.6% and the volume of shares traded on January 10, 2014 was over 1,300% higher than the stock's average daily trading volume. As *MarketWatch* reported, Intercept's stock price "soared another 62% following a surge of 281% on Thursday" after announcing the halting of "the trial of its obeticholic acid drug to treat nonalcoholic steatohepatitis (NASH) ahead of schedule on positive

results." Similarly, Newstex's *Xconomy* reported: "Intercept shares quadrupled to more than $275 a share on Thursday. The next day, after the market fully absorbed the news, the company merely gained another $170 a share, closing at $445.83. Intercept now has a market valuation of $8.6 billion." In total, Intercept's stock price increased $373.44 per share, 515%, in just two days.

45. Defendants' Class Period statements set forth above in ¶¶37-38, 41-43 that caused the unprecedented increase in Intercept's stock price were materially false and misleading when made because Defendants failed to disclose that:

(a) The NIDDK informed Defendants on January 6, 2014 that the agency had found significant lipid abnormalities (increased total cholesterol, increased LDL cholesterol and decreased HDL cholesterol) in patients taking OCA compared to placebo in the FLINT study;

(b) The NIDDK informed Defendants on January 6, 2014 that the FLINT study treatment phase was halted early because the study had satisfied its efficacy endpoint ***and*** because of the finding of significant lipid abnormalities in patients taking OCA compared to placebo; and

(c) Prior to the Class Period, Defendants knew of the significant lipid abnormalities experienced by patients taking OCA in the FLINT trial versus patients on placebo.

VII. DISCLOSURE OF THE TRUTH ABOUT OCA AND THE FLINT TRIAL

46. On Friday, January 10, 2014, at 5:33 P.M. EST, the NIDDK's Dr. Sherker sent defendant Shapiro an email stating:

> The NIDDK and the NASH CRN investigators have had a number of media requests for additional information related to FLINT. We have developed the attached statement as a standardized response to specific media inquiries. However, because the results are preliminary and the trial is ongoing, we are not granting interviews.

47. In language virtually identical to what Dr. Sherker informed Defendants on January 6, 2014, the attached NIDDK statement provided "***FLINT interim results also found disproportionate***

lipid abnormalities (increased total cholesterol with increased LDL and decreased HDL cholesterol) in patients on OCA compound to those on placebo."

48. Shapiro responded to Dr. Sherker's email at 5:53 P.M. EST, writing "I'm about to leave JFK to go home, I suggest we speak on Monday. I had no idea the press release would have the impact it did – it's rather scary!"

49. Three minutes later, at 5:56 P.M. EST, apparently following communication with defendant Pruzanski, Shapiro sent another email to Dr. Sherker trying to stop or delay issuance of the NIDDK's statement. Shapiro wrote "***[t]he lipid information is specific and I think will cause issues***. If this hasn't been issued can we discuss first. At least it would be good to mention that similar findings had been seen previously."

50. Despite Shapiro's request to delay the release of any statement, the NIDDK issued its statement on the interim results of the FLINT trial to the media on the evening of January 10, 2014. The statement provided, in relevant part, "***FLINT interim results also found disproportionate lipid abnormalities (increased total cholesterol with increased LDL and decreased HDL cholesterol) in patients on OCA compared to those on placebo***. As lipid abnormalities are common in people with NASH, following all FLINT patients the full 24 weeks after stopping the drug will help determine whether lipid problems return to pre-OCA levels and weigh potential risks and benefits of the drug." The statement also noted that the "***NIDDK does not typically release interim results as they are preliminary. But as results have already been made public, we are providing limited additional information, giving a broader context for the findings***."

51. Later on the evening of January 10, 2014, after receiving the NIDDK's statement, *The Wall Street Journal* published an article entitled "***NIH Says Patients on Intercept Pharmaceuticals' Liver Drug Had 'Disproportionate Lipid Abnormalities' in Study***." *The Wall Street Journal*

reported "***[p]atients who received Intercept Pharmaceuticals Inc.'s experimental liver-disease drug in a clinical trial experienced more abnormal cholesterol levels than those taking a placebo***, in addition to improvements in their liver health, according to the National Institutes of Health."

52. The next day, Saturday, January 11, 2014, *The Wall Street Journal* published another article, entitled "***Intercept Drug Tied to 'Bad' Cholesterol***." The article repeated the finding that "***patients who received [OCA] had 'disproportionate lipid abnormalities' – including worsened cholesterol levels – compared with patients who received a placebo***." According to the article, Pruzanski tried to minimize the failure to disclose the significant lipid abnormalities to the investing public:

> In a phone interview Friday, Intercept Chief Executive Mark Pruzanski said Intercept also received a statement from the NIH after the market's close Friday about lipid abnormalities. He said earlier in the week, before Intercept announced the positive clinical trial results, the NIH told the company that patients taking the drug had experienced "lipid effects," but the NIH didn't provide any detail.
>
> When Intercept announced the positive study results in a statement Thursday, "we had no concrete data with respect to lipids," Dr. Pruzanski said. "All they gave us that was concrete that we could comment on was the level of statistical significance that was the basis for the decision to stop the study early for efficacy," he said.

53. On Sunday, January 12, 2014, Intercept issued a press release and filed a Form 8-K with the SEC conceding that the NIDDK's January 10, 2014 statement was correct and confirming that patients taking OCA in the FLINT trial had suffered increased lipid abnormalities compared to placebo.

54. As a result of investors learning the truth about the FLINT trial and the NIDDK's finding of disproportionate lipid abnormalities in trial participants who had taken OCA, Intercept's stock price dropped a total of $190.71 per share on Monday, January 13, and Tuesday, January 14, 2014. The 42% decline came on massive volume, as the number of shares traded on both January 13

and January 14, 2014 exceeded Intercept's average daily trading volume by more than 750%. As *The Wall Street Journal* reported, Intercept's stock price declined "after . . . the National of Institutes of Health said Friday that patients taking the drug also suffered more abnormal cholesterol levels." Similarly, *MarketWatch* reported that "***warnings from the [NIH] . . . said that those who used [OCA] . . . experienced 'disproportionate lipid abnormalities'" had sent the Company's shares "into a free fall Monday, which continued into Tuesday," January 14, 2014***.

55. Four months after the initial disclosure of the truth about the FLINT trials, at 6:00 A.M. EDT on May 20, 2014, *TheStreet*, in an article entitled "Intercept Pharma, Government Scientists Spar Over Negative Safety of Liver Drug, Emails Show," reported that documents obtained through a Freedom of Information Act request showed that Defendants knew of the significant lipid abnormalities in patients taking OCA in the FLINT trial before the Class Period. Specifically, according to the article:

> ***Intercept Pharmaceuticals (ICPT) knew last January that abnormal cholesterol levels in patients contributed to the early stopping of a clinical trial involving its liver disease drug obeticholic acid, or OCA, but the company chose to tell investors and lobbied government scientists conducting the trial to downplay the potentially worrisome safety finding, according to newly released emails***.
>
> These emails, made public through the Freedom of Information Act, provide a behind-the-scenes look at the days before Intercept's Jan. 9, 2014 about the OCA clinical trial in patients with nonalcoholic steatohepatitis, or NASH.
>
> In that announcement, Intercept said the clinical trial was stopped early after an interim analysis found a "highly statistically significant improvement" in the livers of patients treated with OCA compared to placebo. . . .
>
> ***But patients treated with OCA were also observed to have "significant lipid abnormalities" not seen in placebo patients, according to a written summary of a phone conversation between National Institutes of Health Program Director Dr. Averell Sherker and Intercept Chief Scientific Officer David Shapiro on Jan. 6***.
>
> ***On this call, Shapiro was told by Sherker that the decision made by the NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to stop the OCA trial early was based on positive efficacy and the negative safety signal***.

56. *TheStreet's* article was published before the markets opened on May 20, 2014. As a direct result of this information being made available to investors, the Company's stock price dropped 14.1% that day on heavy trading volume of over 1.6 million shares. By the end of May 20, 2014, Intercept's stock had fallen $36.66 per share and was trading at $223.34, below the opening price on January 9, 2014. Zacks Equity Research, in an article entitled "Intercept Sinks on Cholesterol Issue," reported "Intercept Pharmaceuticals, Inc.'s (ICPT) shares tumbled 14.1% after a report from The Street disclosed that ***the company had information about the occurrence of abnormal cholesterol levels in its phase IIb study on its lead pipeline candidate, obeticholic acid (OCA) when it came out with a press release on Jan. 9***." The article continued, ***"[b]ased on emails made public through the Freedom of Information Act, it appears that not only did the company fail to disclose these concerns to investors, it also lobbied government scientists conducting the trial to downplay the safety issue associated with the use of OCA***."

57. The next day, May 21, 2014, *The Wall Street Journal* published another article on Intercept, entitled "***Intercept Pharmaceuticals Didn't Disclose Cholesterol Data***." Consistent with *TheStreet*'s article, *The Wall Street Journal* reported that:

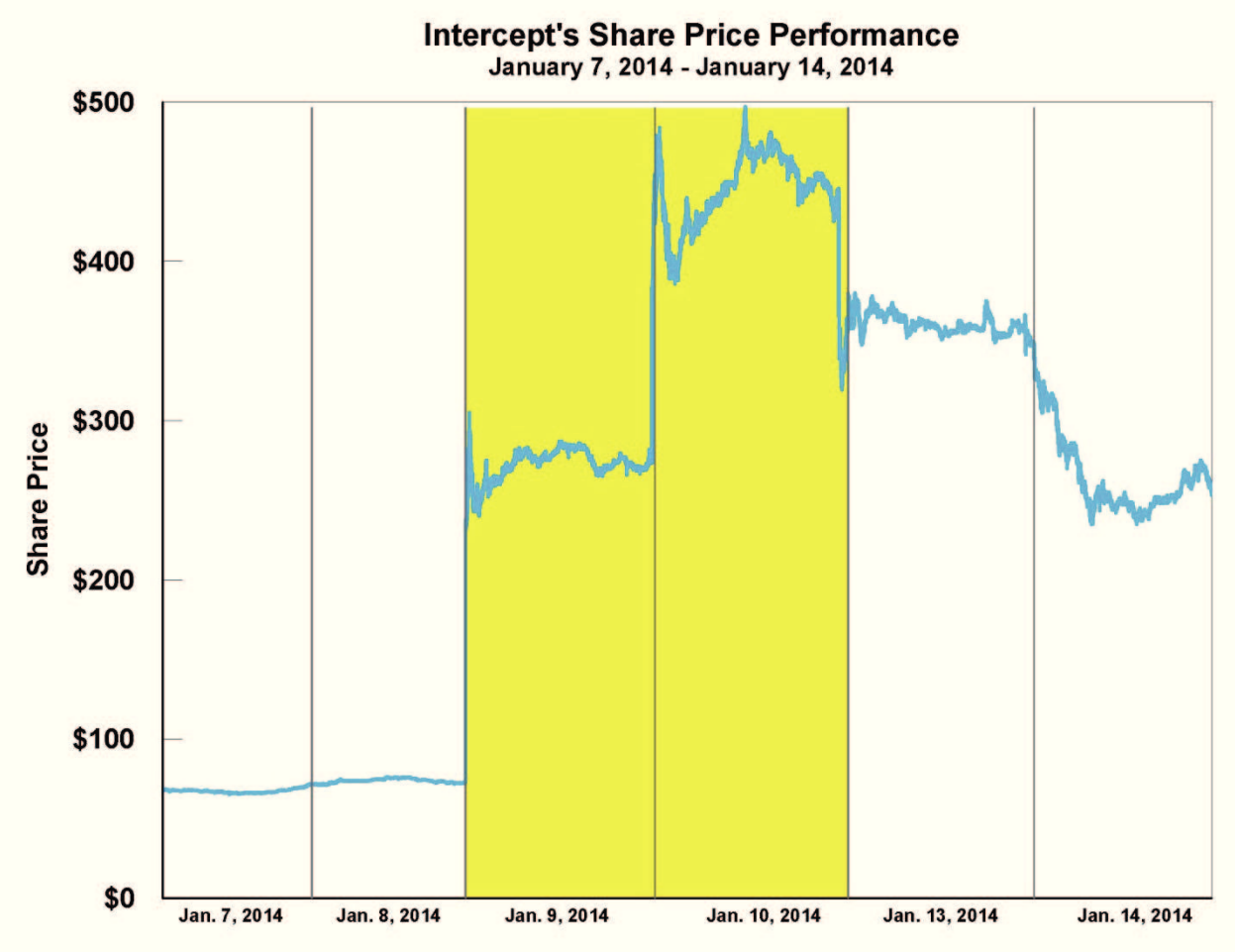
> The emails, obtained through a public records request, indicate that ***Intercept was aware as early as Jan. 6 that the cholesterol issue played a role in the NIH's decision to stop the study***. In its initial Jan. 9 statement on the study's halting, Intercept disclosed to investors only that the study was being discontinued because the drug – obeticholic acid, or OCA – produced significant improvement in patients suffering from a liver disease known as nonalcoholic streatohepatitis, or NASH.
>
> * * *
>
> ***When Intercept issued its news release on Jan. 9 disclosing that the study was stopped early due to efficacy, there was no mention of cholesterol abnormalities or any potential side effects***.

VIII. LOSS CAUSATION/ECONOMIC LOSS

58. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated the price of Intercept stock and operated as a fraud or deceit on Class Period purchasers of Intercept stock by misrepresenting and omitting material information about the FLINT trial. When Defendants' prior misrepresentations and omissions became apparent to the market, beginning on the evening of January 10, 2014, Intercept's stock price fell precipitously, as the prior artificial inflation came out of the price. As a result of their purchases of Intercept stock during the Class Period, Plaintiff and other members of the Class, suffered economic loss, *i.e.*, damages, under the federal securities laws.

59. Defendants' misleading statements and omissions, identified herein at ¶¶37-38, 41-43, had the intended effect and caused Intercept's stock to trade at artificially inflated levels during the Class Period.

60. As a direct result of the disclosures that began the evening of January 10, 2014 and are detailed in ¶¶46-54, Intercept's stock price suffered significant declines. As set forth in the chart below, over the following two trading days, January 13 and January 14, 2014, the price of Intercept stock traded on the Nasdaq plunged $190.71 per share.



61. Intercept's stock price suffered an additional decline of $36.66 per share on May 20, 2014 as a direct result of the further disclosure that day, as set forth in ¶¶55-57, about the FLINT trial and Defendants' knowledge of the significant lipid abnormalities identified in that trial. In total, Intercept's stock price declined $227.32 per share as the prior artificial inflation came out of the price.

62. The decline in Intercept's stock price on January 13 through January 14, 2014 and May 20, 2014, was a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors and the market. The timing and magnitude of Intercept's stock price decline negates any inference that the loss suffered by Plaintiff and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific

factors unrelated to Defendants' fraudulent conduct. Indeed, on January 13 and January 14, 2014, the Nasdaq composite price was flat on average overall volume and the Nasdaq Biotechnology sector was up slightly. Similarly, on May 20, 2014, the Nasdaq composite price and the Nasdaq Biotechnology sector were flat on average overall volume.

63. The economic loss suffered by Plaintiff and other members of the Class was a direct result of Defendants' fraudulent scheme to inflate Intercept's stock price and the subsequent decline in the value of that stock when Defendants' prior misrepresentations and omissions were revealed.

IX. APPLICABILITY OF THE PRESUMPTION OF RELIANCE

64. Plaintiff and the Class are entitled to a presumption of reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact for which there was a duty to disclose.

65. Plaintiff and the Class are also entitled to a presumption of reliance pursuant to *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and the fraud-on-the-market doctrine because, during the Class Period, the material misstatements and omissions alleged herein would induce a reasonable investor to misjudge the value of Intercept's stock and without knowledge of the misrepresented or omitted material facts, Plaintiff and other members of the Class purchased or acquired Intercept securities between the time Defendants misrepresented and failed to disclose material facts and the time the true facts were disclosed. Accordingly, Plaintiff and other members of the Class relied, and are entitled to have relied, upon the integrity of the market prices for Intercept's common stock, and are entitled to a presumption of reliance on Defendants' materially false and misleading statements and omissions during the Class Period.

X. CLASS ACTION ALLEGATIONS

66. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all purchasers of Intercept common stock during the Class Period who were damaged thereby (the "Class"). Excluded from the Class are Defendants and their families, the officers and directors of Intercept, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

67. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Throughout the Class Period, Intercept common stock was actively traded on the Nasdaq, the second largest stock exchange in the world. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are thousands of members in the proposed Class. During the two-day Class Period, there were reported transactions of more than 12.7 million shares of Intercept common stock. Record owners and other members of the Class may be identified from records maintained by Intercept or its transfer agent(s) and may be notified of the pendency of this action using the form of notice similar to that customarily used in securities class actions.

68. There is a well-defined community of interest in the questions of law and fact involved in this case. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

(b) Whether statements made by Defendants to the investing public during the Class Period misrepresented and omitted material facts about Intercept and the FLINT trial of OCA for the treatment of NASH; and

(c) To what extent the members of the Class have sustained damages and the proper measure of damages.

69. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages as a result of Defendants' wrongful conduct

70. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in securities and class action litigation. Plaintiff has no interests which conflict with those of the Class.

71. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for all members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

72. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. Count I is brought pursuant to §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

73. During the Class Period, Intercept, through its officers, management and agents, and the individual defendants, Pruzanski and Shapiro, made or were responsible for the statements specified in ¶¶37-38, 41-43, which they knew or recklessly disregarded were misleading in that they

failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

74. Intercept, the individual defendants and Intercept's officers, management and agents directly and indirectly, by the use of means and instrumentalities of interstate commerce, the mails, and/or the facilities of a national securities exchange: (a) employed devices, schemes and artifices to defraud; (b) made misleading statements and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Intercept common stock during the Class Period. All Defendants are sued as primary participants in the wrongful and illegal conduct charged herein and as controlling persons as alleged below.

75. Intercept, the individual defendants and Intercept's officers, management and agents did not have a reasonable basis for their alleged false statements and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Intercept common stock during the Class Period.

76. Intercept is liable for all materially false and misleading statements and omissions made during the Class Period, as alleged above, including the false and misleading statements made by Intercept's officers and agents, as alleged above, as the maker of such statements and under the principle of *respondeat superior*.

77. Intercept, the individual defendants and Intercept's officers, management and agents, individually and in concert, directly and indirectly, engaged and participated in a continuous course of conduct to conceal adverse material information about OCA and the NIDDK's FLINT trial.

78. The allegations above establish a strong inference that Intercept, as an entity, acted with corporate scienter throughout the Class Period, as its officers and agents had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing the truth about OCA and the FLINT trial. By concealing these material facts from investors, Intercept's share price was artificially inflated during the Class Period.

79. The individual defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. These defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the truth about OCA and the FLINT trial and artificially inflating the price of Intercept common stock.

80. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Intercept common stock. Plaintiff and the Class would not have purchased Intercept common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements and omissions.

81. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Intercept common stock during the Class Period.

COUNT II

For Violation of §20(a) of the Exchange Act Against All Defendants

82. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. Count II is brought pursuant to §20(a) of the Exchange Act, 15 U.S.C. §78t(a).

83. Defendants Pruzanski and Shapiro acted as controlling persons of Intercept within the meaning of §20 of the Exchange Act. Intercept controlled all of its employees and both of the individual defendants. By virtue of their high-level positions, and their ownership and contractual rights, participation in and awareness of OCA and the FLINT trial, as well as their intimate knowledge of the false statements and omissions made by the Company and disseminated to the investing public, defendants Pruzanski and Shapiro had the power to influence and control and did influence and control, directly or indirectly, the Company's decision making, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Pruzanski and Shapiro participated in the January 10, 2014 conference call with investors and analysts and prepared and approved the Company's January 9, 2014 press release, alleged by Plaintiff to be misleading, prior to the press release being issued and had the ability to prevent the issuance of the press release or cause the press release to be corrected.

84. In particular, each of these Defendants had direct and supervisory involvement in the Company's day-to-day operations and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same. By reason of such conduct, Defendants are liable pursuant to §20(a) of the 1934 Act.

85. As set forth above, Defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons,

Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of Intercept's publicly traded common stock during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, and certifying Plaintiff as class representative under Federal Rule of Civil Procedure 23;

B. Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' violations of the federal securities laws, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such equitable, injunctive or other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: June 27, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on June 27, 2014, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on June 27, 2014.

s/ TOR GRONBORG
TOR GRONBORG

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Manual Notice List

The following is the list of attorneys who are **not** on the list to receive e-mail notices for this case (who therefore require manual noticing). You may wish to use your mouse to select and copy this list into your word processing program in order to create notices or labels for these recipients.

- (No manual recipients)